



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

|  |             |                      |                                 |                             |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/595,293   | 04/05/2006  | August Verbruggen    | 50304/014002                    | 7006                        |
| 21559  | 7590        | 09/13/2007           |                                 |                             |
| CLARK & ELBING LLP<br>101 FEDERAL STREET<br>BOSTON, MA 02110 |             |                      | EXAMINER<br>GIBBS, TERRA C      |                             |
|  |             |                      | ART UNIT<br>1635                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>09/13/2007 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

**Office Action Summary**

Application No.

10/595,293

Applicant(s)

VERBRUGGEN ET AL.

Examiner

Terra C. Gibbs

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 38-63 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is a response to Applicant's Preliminary Amendment filed April 5, 2006.

Claims 1-37 have been canceled. New claims 38-63 are acknowledged.

Claims 38-63 are pending in the instant application.

Claims 38-63 are subject to restriction as detailed below:

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 43 and 48, drawn to a method for the *in vitro* modulation of the expression of a IL1 RI target gene in a cell population with an antisense oligomer said method characterized in that it comprises the step on inhibiting mature mRNA function of said IL1 RI target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said IL1 RI mature mRNA of said gene, wherein said exon-bridging antisense oligomer does not comprise a sequence of more than 11 consecutive nucleotides which are complementary to the sequence at the 3' end or the sequence at the 5' end of the exon-exon boundary in said mature mRNA of said IL1 RI target gene, classifiable in class 435, subclass 91.1, for example.
- II. Claim 47, drawn to a method for the *in vitro* modulation of the expression of a IL1 RI target gene in a cell population with an antisense oligomer said

method characterized in that it comprises the step on inhibiting mature mRNA function of said IL1 RI target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said IL1 RI mature mRNA of said gene, wherein said exon-bridging antisense oligomer is complementary to a sequence bridging exons 02-03 in the mature mRNA of the IL1 RI gene, classifiable in class 435, subclass 91.1, for example.

- III. Claims 49 and 50, drawn to a method for the *in vitro* modulation of the expression of a target gene in a cell population with an antisense oligomer said method characterized in that it comprises the step on inhibiting mature mRNA function of said target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said mature mRNA of said gene, wherein said exon-bridging antisense oligomer is selected from SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:21, or a sequence having at least 70% sequence identity with the complementary sequence of the cDNA of the IL1 RI gene corresponding to SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, or SEQ ID NO:21, classifiable in class 435, subclass 91.1, for example. **If this Group is elected, this Group is subject to a further restriction requirement as detailed below.**

- IV. Claim 51, drawn to a method for the *in vitro* modulation of the expression of a target gene in a cell population with an antisense oligomer said

method characterized in that it comprises the step on inhibiting mature mRNA function of said target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said mature mRNA of said gene, wherein said exon-bridging antisense oligomer is complementary to a sequence bridging exons 05-06 of the mature mRNA of the IL1 RI, classifiable in class 435, subclass 91.1, for example.

- V. Claim 52, drawn to a method for the *in vitro* modulation of the expression of a target gene in a cell population with an antisense oligomer said method characterized in that it comprises the step on inhibiting mature mRNA function of said target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said mature mRNA of said gene, wherein said exon-bridging antisense oligomer is SEQ ID NO:24, or a sequence having at least 70% sequence identity with the complementary sequence of the cDNA of the IL1 RI gene corresponding to SEQ ID NO:24, classifiable in class 435, subclass 91.1, for example.
- VI. Claim 54, drawn to an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said antisense oligomer is complementary to a sequence bridging exons 02-03 of the mature mRNA of the IL1 RI gene, classifiable in class 536, subclass 24.5, for example.
- VII. Claim 55, drawn to an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an

exon-bridging antisense oligomer, wherein said antisense oligomer does not comprise a sequence of more than 11 consecutive nucleotides which are complementary to the sequence at the 3' end or the sequence at the 5' end of the exon-exon boundary in said mature mRNA of said IL1 RI target gene, classifiable in class 536, subclass 24.5, for example.

- VIII. Claims 56 and 57, drawn to an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said exon-bridging antisense oligomer is selected from SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:21, or a sequence having at least 70% sequence identity with the complementary sequence of the cDNA of the IL1 RI gene corresponding to SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, or SEQ ID NO:21, classifiable in class 536, subclass 24.5, for example. **If this Group is elected, this Group is subject to a further restriction requirement as detailed below.**

- IX. Claim 57, drawn to an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said exon-bridging antisense oligomer comprises SEQ ID NO:24, classifiable in class 536, subclass 24.5, for example.
- X. Claim 58, drawn to an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an

exon-bridging antisense oligomer, wherein said antisense oligomer is complementary to a sequence bridging exons 05-06 of the mature mRNA of the IL1 RI, classifiable in class 536, subclass 24.5, for example.

- XI. Claims 60 and 63, drawn to a method for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said antisense oligomer is complementary to a sequence bridging exons 02-03 of the mature mRNA of the IL1 RI gene, classifiable in class 514, subclass 44, for example.
- XII. Claims 60 and 63, drawn to a method for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said antisense oligomer does not comprise a sequence of more than 11 consecutive nucleotides which are complementary to the sequence at the 3' end or the sequence at the 5' end of the exon-exon boundary in said mature mRNA of said IL1 RI target gene, classifiable in class 514, subclass 44, for example.
- XIII. Claims 60 and 63, drawn to a method for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said exon-bridging antisense oligomer is selected from SEQ ID NO:6, SEQ ID NO:7, SEQ ID

NO:8, SEQ ID NO:21, or a sequence having at least 70% sequence identity with the complementary sequence of the cDNA of the IL1 RI gene corresponding to SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, or SEQ ID NO:21, classifiable in class 514, subclass 44, for example. **If this Group is elected, this Group is subject to a further restriction requirement as detailed below.**

- XIV. Claims 60 and 63, drawn to a method for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said exon-bridging antisense oligomer comprises SEQ ID NO:24, classifiable in class 514, subclass 44, for example.
- XV. Claims 60 and 63, drawn to a method for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, wherein said antisense oligomer is complementary to a sequence bridging exons 05-06 of the mature mRNA of the IL1 RI, classifiable in class 514, subclass 44, for example.
- XVI. Claims 61 and 62, drawn to a method for producing an exon-bridging antisense oligomer for the inhibition of expression of a target gene comprising determining the exon-exon boundaries in the sequence of a



spliced mRNA, selecting a sequence, and producing an antisense oligomer, classifiable in class 435, subclass 325, for example.

Claims 38-42 and 44-46 links the inventions of Groups I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 38-42 and 44-46. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 53 and 59 links the inventions of Groups VI-X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 53 and 59. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking

Art Unit: 1635

claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other, because of the following reasons:

Groups VI-X are related to Groups XI-XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antisense oligomers for the inhibition of the expression of IL1 RI characterized in that said antisense oligomers are an exon-bridging antisense oligomer of Groups VI-X can be used in a materially different process such as a method for the *in vitro* modulation of the expression of a IL1 RI target gene in a cell population with an antisense oligomer said method characterized in that it comprises the step on inhibiting mature mRNA function of said IL1 RI target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said IL1 RI mature mRNA of said gene, which is a materially different process than the methods for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the

Art Unit: 1635

expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer of Groups XI-XV. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Groups VI-X are related to Groups I-V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antisense oligomers for the inhibition of the expression of IL1 RI characterized in that said antisense oligomers are an exon-bridging antisense oligomer of Groups VI-X can be used in a materially different process such as a method for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer, which is a materially different process than the methods for the *in vitro* modulation of the expression of a IL1 RI target gene in a cell population with an antisense oligomer said method characterized in that it comprises the step on inhibiting mature mRNA function of said IL1 RI target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said IL1 RI mature mRNA of said gene of Groups I-V. Because these inventions are independent or distinct for the

Art Unit: 1635

reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Groups I-V are drawn to methods for the *in vitro* modulation of the expression of a IL1 RI target gene in a cell population with an antisense oligomer said method characterized in that it comprises the step on inhibiting mature mRNA function of said IL1 RI target gene by contacting said cell population with an exon-bridging antisense oligomer directed against said IL1 RI mature mRNA of said gene and are considered to be distinct from the methods for the treatment or prevention of a disease comprising administering an antisense oligomer for the inhibition of the expression of IL1 RI characterized in that said antisense oligomer is an exon-bridging antisense oligomer of Groups XI-XV and the method for producing an exon-bridging antisense oligomer for the inhibition of expression of a target gene comprising determining the exon-exon boundaries in the sequence of a spliced mRNA, selecting a sequence, and producing an antisense oligomer of Group XVI. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of Groups I-V are distinct from the methods of Groups XI-XV and the method of Group XVI since the methods recite distinct method steps and distinct objectives. Furthermore, Groups I-IV are distinct from Groups XI-XV and Group XVI since the three sets of Groups do not overlap in scope as

Art Unit: 1635

each Group set recites materially distinct methods which differ in criteria for success. Because these groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Accordingly, restriction between these Groups is considered proper.

If either of Groups III, VIII, or XIII are elected, claims 49 and 56 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In *re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 49 and 56 specifically claims IL1 RI exon-bridging antisense oligomers selected from SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:21, or a

Art Unit: 1635

sequence having at least 70% sequence identity with the complementary sequence of the cDNA of the IL1 RI gene corresponding to SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, or SEQ ID NO:21. Although the antisense oligomers claimed each target IL1 RI, the instant antisense oligomers are considered to be unrelated, since each antisense oligomer is structurally and functionally independent and distinct for the following reasons: each antisense oligomer has a unique nucleotide sequence and each antisense oligomer targets a different and specific region of IL1 RI. As such the Markush/genus of antisense oligomers listed in claims 49 and 56 are not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the antisense oligomers claimed in claims 49 and 56 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense oligomers. In view of the foregoing, one (1) antisense oligomer is considered to be a reasonable number of nucleotide sequences for examination. Accordingly, Applicants are required to elect one (1) antisense oligomer from claims 49 and 56. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct antisense oligomer sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Also, because these inventions are independent or distinct for the reasons given above and there would be a

Art Unit: 1635

serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in

Art Unit: 1635

the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the



Art Unit: 1635

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg

September 10, 2007

/Terra Cotta Gibbs/